INSTITUTIONAL PROFILE

All institutions should complete this form and update it as needed to ensure accuracy.

SECTION 1. This section should be completed by any institution that may cede review to an external Reviewing IRB. A potential Reviewing IRB will review and consider the information in this section during the ceding process.

1. Name of Institution: _____

2. List all other names by which the institution is known.

3. List all organizations that are considered components under this institution's FWA.

4. Is your institution a covered entity under HIPAA for research activities? ☐ Yes ☐ No

5. List any components under your FWA that are covered entities under HIPAA for research activities.

6. If your institution and/or components are a covered entity, what are the HIPAA authorization/informed consent document requirements?

7. What is your institution policy on use of short form consents for non-English speaking individuals?

8. What is the age of majority in your state? _____

This information was obtained from Institutional Profile as part of SMART IRB, which is funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, grant number UL1TR001102-04S1. 06-05-2018

9. What is your institution's interpretation of state law regarding when minors in your state can consent for themselves?

10. Describe any broad laws or institutional requirements that would be applicable to all protocols reviewed on behalf of the institution.

11. Has your institution implemented flexible options with regard to review and approval of research at your institution (e.g. have you "unchecked the box")? ☐Yes ☐ No

- If Yes, provide details.

12. If your study site agrees to cede review, would you like to be notified of each of the IRB's determinations?
☐Yes ☐ No

- If Yes, provide an email and phone number contact:

SECTION 2. This section should be completed by any institution that may serve as a Reviewing IRB. A potential Relying Institution will review and consider the information in this section during the ceding process.

13. Is your institution willing to serve as an IRB of record (Reviewing IRB) for other institutions? ☐Yes ☐ No

14. Name of the institution's IRB(s): _____

15. How will the institution's IRB policies be made available to Relying Institutions?

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16. In the past five years, have there been any letters of findings from OHRP or FDA as a result of investigations or inspections of the institution's IRB? ☐Yes ☐ No
    - If yes, please explain.

17. As a Reviewing IRB, would you be willing to serve as the Privacy Board for other institutions? ☐Yes ☐ No

18. Will the institution's IRB(s) require a listing, review, and/or approve of all study personnel from each Relying Institution? ☐Yes ☐ No
    - If yes, please describe how this will be provided, reviewed, and updated.

19. Please indicate how your institution has assessed the quality of its IRB/HRPP?

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